CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA

Methyl dodecylbenzyl trimethyl ammonium chloride SB 950-453 Tolerance # 50071

September 10, 1987

I. DATA GAP STATUS

Chronic rat: Data gap, inadequate study, possible adverse effect indicated.

Chronic dog: Data gap, inadequate study, no adverse effect indicated.

Onco rat: Data gap, no study on file.

Onco mouse: Data gap, no study on file.

Repro rat: Data gap, no study on file.

Terato rat: Data gap, no study on file.

Terato rabbit: Data gap, no study on file.

Gene mutation: Data gap, no study on file.

Chromosome: Data gap, no study on file.

DNA damage: Data gap, no study on file.

Neurotox: Not required at this time.

Note: Toxicology one-liners are attached

** indicates acceptable study

Boldface indicates possible adverse effect

Summary prepared by M. Harnois, 9/10/87

FILE: SB453MET.MH

II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

CHRONIC

RAT

50238-086 12304 "Final report on the effect of adding various concentrations of hyamine 2389 [alkyl (C-9 to C-15) tolyl methyltrimethyl ammonium chlorides] to the diet of rats for a period of two years" (Medical College of Virginia, Richmond, VA 1/21/53). Hyamine 2389 in diet mix was fed at concentrations of 0, 50, 200, 1000, 2500 and 5000 ppm (AI) to albino rats (10M, 10F/group) for 2 years. All died in the 5000 ppm group by 30 weeks. Other effects were decreased body weights (2500 ppm after 30 weeks) and distended caeca (1000 ppm and above at necropsy). Initial review (Aldous, 6/4/85) found insufficient information for assessment; subsequent review (Harnois, 9/10/87) for tox. summary noted study was unacceptable, not upgradeable (summary data only, insufficient numbers of animals, inadequate necropsy data, no test substance assay).

50421-002 23487 Summary article on data in 12304. (Aldous, 6/5/85)

DOG

50238-086 38553 "Final report of one-year feeding study in which various dietary levels of hyamine 2389 were administered to dogs" (Medical College of Virginia, 5/28/52). Hyamine 2389 in diet mix at levels of 5, 100, and 500 ppm was fed to mongrel dogs (3/group, no sex or previous history given) for 1 year. Insufficient information; no adverse effects reported. Apparent NOEL (chronic))= 500 ppm as administered. Unacceptable (no individual data, too few animals, incomplete animal description, inadequate hematology and necropsy

sampling, no testing of substance, no food consumption data for individuals, generally only a summary and more pilot-type study than chronic). (Aldous, 6/4/85). Subsequent review (Harnois, 9/10/87) documented Hyamine 2389 as a mixture of SB453 and SB454.